National Institute of Mental Health

REQUEST FOR PROPOSAL NO.:	AMENDMENT NO. 1 RFP NO. NIMH-01-DS-0002
TITLE:	"Data Management Support and Clinical Trial Coordination for NIMH"
OMB No.:	0990-0115
ISSUED BY:	Patricia L. Gibbons Contracting Officer National Institute of Mental Health Contracts Management Branch, ORM 6001 Executive Blvd., Rm. 6107 MSC 9603 Bethesda, Maryland 20802-9603
DATE ISSUED:	Thursday, December 15, 2000
PURCHASE AUTHORITY:	Public Law 95-218 as amended
SMALL BUSINESS SET-ASIDE:	Yes, 100% Set-Aside, NAICS Code 541519
JUST IN TIME:	Yes
OFFER EXPIRATION DATE:	Offers will be valid for 120 days unless a different period is specified by the Offeror

To all Offerors:

The purpose of this amendment is to:

1. Extend the Proposal Due Date until Wednesday, January 24, 2001, 3:30 PM EST
2. Correct the NAICS Size Standard to $18 Million
3. Respond to offerors' questions as follows:

Q1. Is there an incumbent contractor? And are there existing contracts that this RFP is replacing?

A1. There is no incumbent contractor nor any existing contracts.

Q2. Will the Government provide a bidders list?

A2. The NIMH does not maintain a bidders list.

Q3. Are there any font size restrictions or page limitations?
A3. There are no font size restrictions or page limitations.

Q4. What weighting factor is past performance given in the evaluation process?
A4. Past performance is evaluated however is not a weighted factor.

Q5. Since this sample task order appears to be an on going trial (study number MH5368, NCT00000381), are current contractors involved eligible to bid this RFP? Are there current contractors involved or is it done completely internally?
A5. The sample trial was referenced to give offerors an idea of the type of clinical trials that NIMH is conducting. NIMH intends that the sample task order will standardize the budget responses between offerors.

Q6. Please confirm the reference to Attachment #5 in Section 4 of the RFP, Business Proposal.
A6. Amendment No. 1 removes the reference to Attachment #5 in Section 4, Separation of Technical and Business Proposals, of the RFP. Correction is also made to the reference of Attachment #5 under Section 2 (b) TECHNICAL PROPOSAL, 2 (c) BUSINESS PROPOSAL, and Section 3 Proposal Summary and Data Record to read Attachment #6.

Q7. The solicitation indicates that cost data be placed in the management volume. Management of the trials is an important part of the technical success of drug trials and as such should be included in the technical proposal or as a separate management volume. Will the technical evaluators be provided with the cost/management volume? Will the government consider a separate technical, management, and cost volume?
A7. The evaluation panel will consider each offerors technical merits on its' own in addition to the cost submitted in accordance with the cost form located at as a part of their technical proposal.

Q8. The RFP does not include an estimated number of FTE's necessary to complete the work or any estimate of the number of trials which will need data management support and/or clinical trial coordination. Can NIMH estimate the number of FTE's or labor hours which will be required in performance of this contract?
A8. NIMH anticipates awarding all Task Orders on a Fixed-Price basis. Therefore, it will be up to the Contractor to determine labor needs. Additionally, NIMH also anticipates awarding a minimum of one (1) Task Order and up to ten (10) additional Task Order's during the period of performance.

Q9. Does the fringe rate have to be separate from the overhead/indirect rate. Can we combine the two rates?
A9. NIMH expects that the contractor will structure the budgets and bill in accordance with their standard business practices.

Q10. Please address the timing of the Task Orders.

A10. NIMH anticipates awarding the first Task Order at the time of contract award. In regards to awarding additional Task Orders, NIMH expects that one – two Task Orders will be awarded each year of the contract.

Q11. Referencing the Statement of Work (SOW), II Services to be Performed, Section 1, under Specific Requirements; please provide clarification to the last sentence: "Possible tasks the Contractor may be required to perform include the following (however, note Task XIV below). Please explain why Task XIV is noted.

A11. The reference is incorrect and is hereby deleted from the SOW.

Q12. Is there a requirement to have a local office in the Bethesda area? Will the government provide on site office facilities?

A12. There is not requirement to have a local office in the Bethesda area and NIMH does not envision providing on site facilities.

Q13. In terms of budgeting for the sample task order, can you further define the scope of the clinical trial? For example which phases of the trial are included and what is the end result?

A13. For budgeting purposes, please assume that the trial allows one (1) year to recruit patients, all outpatients, and all outpatient treatment.

Q14. Regarding the hypothetical Task Order included for pricing purposes in the Business Proposal Instructions, are we to assume that all Tasks (I-XV) outlined in the SOW are to be included in the pricing proposal?

A14. Yes

Q15. Is it expected that the contractor use or interface to any current automated systems? If so, please specify.

A15. NIMH does not anticipate the contractor to interface with any current automated systems.

Q16. Are the clinical trials to be conducted in coordination with a Pharmaceutical company under an IND? If the trials are under an IND, are they Phase I, II, or III?

A16. NIMH does not expect current clinical trials to be conducted with a pharmaceutical company under an IND, but it is possible that future trials could. Most NIMH clinical trials are Phase IV, post-marketing trials.

Q17. Are any of the trials a sub-study to a clinical trial being conducted by a pharmaceutical company at present? or Are the trials a follow-up to an NDA submission?

A17. None of the NIMH clinical trials are a sub-study or follow-up to an NDA submission.

Q18. Are the compounds to be used in the trials approved and marketed? If so, are these trials Phase IV/Post Marketing Surveillance?

A18. The medications used in NIMH clinical trials are FDA approved and usually involve Phase III – IV post marketing surveillance.

Q19. Are the trials in-patient or outpatient?

A19. NIMH typically conducts outpatient clinical trials.

Q20. Is the patient population both adult and pediatric?

A20. Yes, but not usually mixed within a trial. That is, a trial is either in an adult population, a pediatric population or an adolescent population.

Q21 Is the end point of each trial including primary and secondary efficacy variables identified or to be determined? Is the protocol design of each trial established or to be established by the clinical expert identified to manage the trials? Likewise, is it expected that entire protocols will be developed by the clinical expert?

A21. Usually protocols specify the endpoints. Sometimes, protocols are not fully developed and the contractor will help the group develop and/or finalize protocols.

Q22. Is the main purpose of the research to produce a clinical trial report to be used in a submission or for the purpose of publication only?

A22. The main purpose of research is to answer important public health questions and disseminate the information appropriately, e.g. scientific journal publications, presentations at scientific meetings, etc. (See also SOW Task XII).

Q23 Is it expected that the clinical, therapeutic expert will also be the statistical expert or will a biostatistician also be needed?

A23. Please reference Task I (Work Plan), 1a and 1b. Some trials may have a biostatistical consultant as part of the team and some trials may rely on the biostatistical expertise provide by the coordinating center contractor. The requirement for level of biostatistical expertise at the coordinating center will be specified in each task order.

Q24. Is it expected that the investigator sites chosen will have research experience or be research naive and require extensive training?

A24. NIMH has historically experienced a mixture of research experience with clinical sites and most have had some experience.

Q25. If naï ve sites are to be used, will it be necessary to provide study coordinators?

A25. Clinical sites are expected to hire their own study coordinators.

Q26. Are the professional data entry personnel to be provided by the contractor in addition to the study coordinators?

A26. If it is decided to use professional data entry personnel, NIMH expects that the position would not be the same as that of study coordinator.

Q27. Is it expected that a pre-study, qualification visit will be conducted at each site?
A27. It depends on how well a site is known and the requirements of the trial.

Q28. Is an investigator meeting anticipated and/or site initiation visits planned?
A28. Please plan for one (1) investigator meeting per year. Also, please plan to include initial training and site initiation visits.

Q29. Is it expected that the site raters will be study staff other than the coordinators?
A29. Yes.

Q30. Is it expected that study drug packaging and study supplies will be provided by the pharmaceutical companies or will an independent vendor be required?
A30. NIMH has historically experienced the generosity of the pharmaceutical industry to donate medication/placebo. Drug packaging has been provided by both the individual pharma's and under separate vendor agreements.

Q31. Will the medical monitoring to be provided include the responsibility of Serious Adverse Event reporting to the FDA?
A31. Yes.

Q32. Will central laboratories be required?
A32. Central laboratories are usually required under NIMH trials.

Q33. Is it anticipated that advertising will be necessary for patient recruitment, news, media, radio, etc.?
A33. Yes.

Q34. Are site visits only to be conducted at least once a year or is a recommended site monitoring plan anticipated to be provided?
A34. The contractor is expected to propose a site monitoring plan.

Q35. Are site close-out visits to be conducted?
A35. NIMH expects that the contractor will take this under consideration when proposing a budget on any given task order.

4. Include Performance Requirements Summary

The NIMH expects the successful contractor to perform the contract with outstanding technical capability and in a highly cost effective/efficient manner. Therefore, in keeping with these standards, each offeror is required to submit a surveillance plan with their Technical Proposal (see the attached sample Performance Requirements Summary). The NIMH will use the surveillance plan to determine whether the contractor is meeting the standards set out in the Statement of Work.

PERFORMANCE REQUIREMENTS SUMMARY

SAMPLE

Tasks	Standards	Maximum Allowable Degree of Deviation (AQL)	Method of Surveillance	Maximum Payment Percentage for Meeting /Exceeding the AQL
Prior to delivery of new software, demonstrate the operational capability of the system software.	Functionality of the software to meet required systems architecture and processing capabilities.	All requirements mandated by law or regulation must be 100% compliant.	Independent verification and validation for testing new releases of software to determine that previous functionality is maintained.	100% payment for meeting all mandated requirements. Nonconformance is unacceptable.